DEC STD 131-0 Traceability Policy

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ABSTRACT: This standard defines the Digital requirements for the traceability of component parts, subassemblies, and serialized finished products manufactured, marketed, or sold by Digital. Repaired or refurbished parts, subassemblies, and serialized finished products are also covered by this traceability standard.

APPLICABILITY: Facility Managers have the final responsibility for defining, documenting, and implementing a process for ensuring compliance with traceability requirements.

STATUS: APPROVED 21-Jun-1991; use VTX SMC for current status.

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1 INTRODUCTION

Traceability is the process of tracking a product and its component parts through the assembly and test processes specified at design. This ensures that the finished products meet their intended level of performance and regulatory compliance at the end user's site.

Given the market, complexity, and volume of products that Digital manufactures, it has been determined by the Management Committee that a product traceability program is mandatory within Digital.

This decision was made to minimize the potential impact of an accident of undetected failure in our products that could require a product recall or some other product-related liability.

Every Digital manager is responsible for ensuring that products meet the company's goal for high-level performance.

NOTE

The following are examples of processes for providing traceability that are currently in use at various manufacturing sites.

- **Bar code labeling**
- **Automated warehouse system**
- **INFINET**
- **System T (auto input to recall data base)**
- **Manufacturing sites with hard copy process:**
  - **— Traveler, ship log, usage, and control procedures**
  - **— Configuration history system operational procedure**

1.1 PURPOSE

This standard states the requirements for product traceability necessary to comply with legal requirements, market needs, and to minimize the exposure and possible impact on Digital in the event of product recall or litigation.

This standard is meant to complement the following standards. These standards detail the methods for markings and identifications and should be consulted for implementation of a traceability program.

DEC STD 012-0 Part Identification Standard

DEC STD 012-1 Unified Numbering Code: Document Identification Conventions Including Mnenonic Codes

DEC STD 012-2 Unified Numbering Code for Part Identifier Class Codes

DEC STD 012-5 Unified Numbering Code (UNC) - Manufacturing Control Part Numbering Conventions

DEC STD 012-6 Enterprise Integration Services (EIS) Numbering Conventions

DEC STD 012-7 Unified Numbering Code - 74 Class Part Numbering Conventions and Assignment Procedures

DEC STD 012-8 Digital Service Part Identifier Conventions

DEC STD 012-10 Conventions Used to Assign Part Identifiers with Significance in Part Classes 11, 15, 19, 21, and 91

DEC STD 131-1 Controlled Components details traceability requirements of controlled components.

DEC STD 131-2 Telecommunications Controlled Components details traceability requirements of telecommunication-controlled components.

DEC STD 178-0 Digital Identification Marking Requirements - Introduction

DEC STD 178-1 Digital Marking Requirements for Piece Parts

DEC STD 178-2 Digital Marking Requirements for Subassemblies: Field Replaceable Units (FRU) and Non-Field Replaceable Units

DEC STD 178-3 Digital Marking Requirements for Completed Products Intended to be Sold

1.2 SCOPE

The standard encompasses the worldwide responsibility of manufacturing, distribution, and customer service for compliance to traceability requirements.

1.3 RESPONSIBILITIES

Site managers have the final responsibility for defining, documenting, and implementing a process for traceability compliance.

They are responsible for maintaining the necessary records in a format that will allow recovery of these records in the event of a product recall or any other investigation. A documented process must be available by the site that delineates the steps taken to obtain, validate, and maintain these records.

NOTE

In this document, Facility Manager refers to the person with responsibility and authority for the specific site, such as Plant Manager, Distribution Center Manager, POM Site Manager, and so on.

1.4 DEFINITIONS

The following definitions explain the basic terms used in this standard.

forward traceability - the ability to trace any component, subassembly, or serialized finished product from source through destination.

backward traceability - The ability to trace any component, subassembly, or serialized finished product from its destination back to its source.

component part - any part, material, or substance acquired by digital for the manufacture of subassemblies or serialized finished products.

Regulatory Controlled Part (RCP) - Any component, material, or substance acquired by Digital for the manufacture of finished products, which, due to mechanical, chemical, or electrical properties could, in a given application, cause a malfunction that may require tracing of that part for corrective action.

NOTE

These parts are listed in the regulatory reports issued by Engineering and are controlled by external agencies. Markings and agency logos prescribed by these agencies shall be adhered to.

subassembly - any combination of component parts.

serialized finished product - Any combination of component parts or subassemblies that has a serial number.

2 TRACEABILITY CRITERIA

2.1 FORWARD TRACEABILITY

Given a vendor name and lot number for a component part, the facility must be able to identify all the subassemblies or finished products by serial number in which these components were assembled and determine the shipped-to location of each unit.

2.2 BACKWARD TRACEABILITY

Given a serial number of a unit or finished product produced by the facility, the facility must be able to identify by vendor and lot number, serial number or tracking number and all component parts used in the assembly of the product that require traceability.

NOTE

Selection of component parts that are placed under the traceability process shall be determined by the appropriate product safety engineer. This list must include Regulatory Controlled Parts (RCPs), as a minimum.

3 TRACEABILITY REQUIREMENTS

The following minimum requirements shall be met for a facility to comply with this standard to achieve a traceability process. Specifically, the process shall follow the procedure in subheads 3.1, 3.2, and 3.3. All facilities using bar code shall implement in accordance with *DEC STD 047-0 Bar Code Symbology* to automate data collection for traceability.

3.1 INCOMING

The following directions apply to component parts, subassemblies, or serialized finished products.

1. Record the part number, model number, serial number, and revision number.
2. Record the vendor name or vendor code and vendor lot.
3. Record the following manufacturing information.
    - Date code or lot number

- Manufacturing date

The traceability process shall include the capability of recording the previous information at the time of receipt of the component parts, subassemblies, or serialized finished product at the manufacturing or repair site. The process shall also have the capability implemented in the vendor's process to provide the same information to Digital (on request) for each shipment of material to a Digital facility.

3.2 PROCESS

The process that occurs between the incoming procedure in tht text under subhead 3.1 and the outgoing procedure in the text under subhead 3.3 shall be recorded.

3.3 OUTGOING

Apply the following procedure to component parts, subassemblies, or serialized finished product.

1. Record any of the following that is applicable: part number, codes, serial number, model number, and revision level shipped.
2. Record the date shipped.
3. Record the shipped to address.
4. Record the recipient's name.

4 TRACEABILITY KEY POINTS SUMMARY

The following key points summarize the requirements for the function involved to implement the steps needed to trace component parts, subassemblies, and serialized finished products.

4.1 SAFETY/REGULATIONS ENGINEERING

For each product undergoing *DEC STD 119-0 Digital Product Safety - Introduction and General Requirements* testing, define and document the Index of Controlled Components.

1. Document the process by which the component parts, subassemblies, or serialized finished product have been assembled, tested, packaged, and shipped.
2. Identify the Digital revision level of the finished product by part number and serial number.
3. For each product being introduced,transferred or repaired, define and document in the product manufacturing/quality plan, all the documentation required to be controlled under a formal record retention system.
4. The extent of this documentation shall comply with the requirements of the corporate record retention schedule. Refer to *DEC STD 101-0 Manufacturing Operations Plan for Assembly, Inspection, and Test: Policy and Requirements*.
5. Record the shipped-to destination of the component parts, subassemblies, or serialized finished products.
6. Provide for compatibility of the local traceability system with other Digital vendors and customer sites, when applicable.

7. Develop the necessary processes to achieve backward traceability from a serial number to the component parts, subassemblies, or serialized finished products used within the facilities process.

APPENDIX A REFERENCED DOCUMENTS

A.1 EL-Class Digital Documents

EL-Class Number	Document Title
EL-00012-00	*DEC STD 012-0 Part Identification Standard*
EL-00012-01	*DEC STD 012-1 Documentation Identification Conventions Including Mnemonic Codes*
EL-00012-02	*DEC STD 012-2 Unified Numbering Code for Part Identifier Class Codes*
EL-00012-05	*DEC STD 012-5 Unified Numbering Code (UNC) - Manufacturing Control Part Numbering Conventions*
EL-00012-06	*DEC STD 012-6 Enterprise Integration Services (EIS) Numbering Conventions*
EL-00012-07	*DEC STD 012-7 Unified Numbering Code - 74 Class Part Numbering Conventions and Assignment Procedures*
EL-00012-08	*DEC STD 012-8 Digital Services Part Identifier Conventions*
EL-00012-10	*DEC STD 012-10 Conventions Used to Assign Part Identifiers with Significance in Part Classes 11, 15, 19, 21, and 91*
EL-00047-00	*DEC STD 047-0 Bar Code Symbology Criteria*
EL-00101-00	*DEC STD 101-0 Manufacturing Operations Plan for Assembly, Inspection, and Test: Policy and Requirements*
EL-00119-00	*DEC STD 119-0 Digital Product Safety - Introduction and General Requirements*
EL-00131-01	*DEC STD 131-1 Controlled Components*
EL-00131-02	*DEC STD 131-2 Telecommunications Controlled Components*
EL-00178-00	*DEC STD 178-0 Digital Identification Marking Requirements - Introduction*
EL-00178-01	*DEC STD 178-1 Digital Marking Requirements for Piece Parts*
EL-00178-02	*DEC STD 178-2 Digital Marking Requirements for Subassemblies: Field Replaceable Units (FRU) and Non-Field Replaceable Units*
EL-00178-03	*DEC STD 178-3 Digital Marking Requirements for Completed Products Intended to Be Sold*

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